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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MARTIN, PAUL C	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 12/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/517,853	YONEHARA ET AL.	
	Examiner	Art Unit	
	Paul C. Martin	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-19 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/14/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-19 are pending in this application and were examined on their merits.

Claim Objections

Claims 4 and 5 are objected to because of the following informalities: Sodium Lauryl Sulfate (SLS) and Lithium Lauryl Sulfate are not in fact, sulfonic acid compounds but are *sulfuric acid* compounds. The same problem exists with including Sodium Nitrite and Potassium Nitrite under *Nitro*-compounds. It is suggested that the claims be amended to say, "wherein the 1) Sulfonic Acid or 2) Nitro compound is at least one selected from the group consisting of...or 1) Sodium Lauryl Sulfate or Lithium Lauryl Sulfate / 2) Sodium Nitrite or Potassium Nitrite. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: The omission of a measuring step, i.e., the measurement of the amount of analyte derived substance formed from the redox reaction.

Claims 6 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "caused by" in Claim 6 is deemed indefinite as there seems to be a missing critical method step from the point of reducing the oxidizing substance to the formation of a color by some reaction. The term "by causing" in Claim 10 is deemed indefinite as it is not clear at which point that fructosyl amino acid oxidase has been added to the reaction mixture.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 14 and 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-14 of copending Application No. 10/521234. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 7-14 of Application No. 10/521234 teach the specifics of the instantly claimed invention absent the specific citation wherein hemoglobin is present in the sample. It is well known in the art that hemoglobin is found in the blood and that patients with excess glycated proteins are at a higher risk for Diabetes. Although the Claims of Application No. 10/521234 do not specifically teach wherein hemoglobin was part of the sample, one of ordinary skill in the art would have been motivated to measure a glycated protein in a sample containing hemoglobin, such as blood, in order to assess a patient for Diabetes.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim1 is rejected under 35 U.S.C. 102(e) as being anticipated by Komori *et al.* (US 2002/0025546 A1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Komori *et al.* teaches a method for measuring an analyte in a sample containing hemoglobin by using a redox reaction, and adding a nitro compound (2-(4-iodophenyl)-3-(2,4-dinitrophenol-5-(2,4,-disulfophenyl-2H-tetrasolium salt, hereafter referred to as WST-3) to the sample to as to eliminate the influence of the hemoglobin or hemoglobin degradation products contained in the sample. (Column 1, Lines 4-18).

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Oshiro *et al.* (1982).

Oshiro *et al.* teaches a method of measuring an analyte in a sample containing hemoglobin by using a redox reaction. Specifically, Oshiro *et al.* teaches the measurement of hemoglobin in a hemoglobin-containing sample by oxidizing reduced hemoglobin with SLS. A byproduct of this reaction is the inherent elimination of any further influence of hemoglobin in the sample. Oshiro *et al.* teaches the addition of both SLS and Sodium Nitrite to the sample in the practice of the method as well.

As the SLS added by Oshiro *et al.* is a main component of the redox reaction between SLS and hemoglobin, it is necessarily added *prior* to the redox reaction. Further, the method of Oshiro *et al.* provides for the formation of a oxidizing substance derived from the analyte (hemoglobin) which then reduces SLS, enabling the measurement of the formed SLS-Hb derived from hemoglobin by a redox reaction and the determination of the amount of hemoglobin from the amount of formed SLS-Hb.

Although Oshiro *et al.* did not add the compounds to the hemoglobin-containing samples for the same intended purpose as the applicant, they non-the-less performed the described method and thereby anticipated the claims 1-5. Claims 1-5 do not state implicitly to what "analyte" they are drawn to, and reading the Claims with the broadest reasonable interpretation, the metes and bounds of the Claims 1-5 are fulfilled by the method described by Oshiro *et al.* using hemoglobin itself as the analyte.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komori *et al.* (US 2002/0025546) in view of Oshiro *et al.* (1982) and ATSDR Course: SS3054 (2001).

Komori *et al.* teaches a method for measuring analyte in a sample containing hemoglobin or hemoglobin degradation products by using a redox reaction, comprising adding a nitro compound to the sample to eliminate the influence of the reducing substances contained in the sample, forming an a reducing substance or an oxidizing substance derived from the analyte, and determining the amount of the from the quantity of the formed substance. (Page 1,Column 1, Lines 4-18)

Komori *et al.* teaches adding both the nitro compound WST-3 and a surfactant to the sample. (Page 4, Column 1, Lines 1-20)

Komori *et al.* teaches that the redox reaction is a color development reaction caused by reducing the oxidizing substance derived from the analyte (hydrogen peroxide) and oxidizing a substrate that develops color by oxidation using an oxidase (peroxidase), wherein the amount of oxidizing substance developed is quantified by the degree of color development. (Page 12, Column 2, Claims 13 and 14)

Komori *et al.* teaches that the degree of color development is measured by measuring at a wavelength for detecting the substrate. (Page 5, Column 1, Lines 4-11)

Komori *et al.* teaches that the analyte can be glycated protein, glycated peptides, or glycated amino acids and hydrogen peroxide is formed as the oxidizing substance derived from the analyte by causing a fructosyl amino acid oxidase (FAOD) to act on the analyte, (Page 3, Column 1, Lines 12-19) and the addition of a surfactant and a nitro compound to the sample before causing the FAOD to act on the analyte. (Page 4, Column 1 Lines 5-16 and Column 2, Lines 18-21)

Komori *et al.* teaches the use of the above steps with a color developing substrate N-(carboxymethylaminocarbonyl)-4,4'-bis(dimethylamino)diphenylamine sodium salt, a combination of Trinder's reagent and 4-aminoantipyrine (Page 4, Column 2, Lines 39-43)

Komori *et al.* teaches the glycated protein can be glycated hemoglobin and the hemolyzed sample is obtained by hemolyzing erythrocytes (Page 3, Column 1, Lines 3-11)

Komori *et al.* teaches the addition of a surfactant to a sample, the surfactant concentration between 0.01 to 5% by weight, (Page 4, Column 1, Lines 13-15) and the addition of the nitro compound to a sample so that its concentration is between 0.4 to 200mmol/L when the concentration of blood cells in the sample is from 1-10% by volume. (Page 4, Column 1, Lines 19-30)

Komori *et al.* does not teach the use of a sulfonic acid compound or any of the claimed nitro compounds.

Komori *et al.* does not teach the use of N,N,N',N',N",N",-hexa(3-sulfopropyl)-4,4',4"-triaminotriphenylmethane hexasodium salt, or N,N,N',N',N",N",-hexa(2-hydroxy-3-sulfopropyl)-4,4',4"-triaminotriphenylmethane hexasodium salt, or 10-(carboxymethylaminocarbonyl)3,7-bis(dimethylamino)phenothiazine sodium salt, or 10-(methylaminocarbony)3,7-bis(dimthylamino) phenothizine sodium salt.

Komori *et al.* does not teach the addition of a sulfonic acid compound to a sample so that its concentration is between 0.05-200mmol/L when a concentration of blood cells in the sample is 1% by volume.

Komori *et al.* does not teach the addition of the nitro compound to a sample so that its concentration is between 0.05-500mmol/L when a concentration of blood cells is 1% by volume.

Komori *et al.* does not teach the addition of a sulfonic acid compound and a nitro compound to a sample so the their respective concentrations are 0.05 to 200mmmol/L and 0.05 to 250mmol/L when a concentration of blood cells in the sample is 1% by volume.

Oshiro *et al.* teaches the use of the sulfonic acid compound Sodium Lauryl Sulfate (SLS) in a method to quantify normal and abnormal hemoglobin in a blood sample. (Page 86, Table 1).

Oshiro *et al.* teaches that SLS binds to protein and has surfactant activity, and can hemolyze erythrocytes. (Page 87, Column 2, Lines 1-10).

The ATDSR Course: SS3054 teaches that nitro compounds react with hemoglobin in the blood to oxidize deoxyhemoglobin, forming methemoglobin. (Page 9, 16-22). Examples of known hemoglobin oxidizers are nitrobenzene, nitrite salts nitroanilines, and nitrophenols.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to use SLS, a well known detergent capable of acting as a surfactant, and known to have been used in blood/hemoglobin assays, and the ordinary artisan would have been motivated to use SLS or any other sulfonic acid compound as the surfactant used in the method of Komori *et al.*

As it was known in the art at the time of the instant invention that aromatic nitro compounds oxidize hemoglobin and neutralize its interfering characteristics in redox reactions, it would have been obvious to the ordinary artisan to include a nitro compound in the pre-treatment step prior to the redox reaction to neutralize the effects of any free hemoglobin which could otherwise have interfered with the impending redox reaction.

Although Komori *et al.* did not teach the color developing substrates of Claim 13, it is deemed that the 10-(carboxymethylaminocarbonyl)3,7-bis(dimethylamino) phenothiazine sodium salt and 10-(carboxymethyl-4-benzaminocarbonyl)3,7-bis(dimethylamino) phenothiazine sodium salt are obvious variants of N-(carboxymethylaminocarbonyl)-4,4'-bis(dimethylamino) diphenylamine sodium salt found in Claim 12.

The ordinary artisan would have had a reasonable expectation that the 10-(carboxymethyl...) compounds would have acted as functional equivalent color developing substrates to N-(carboxymethylaminocarbonyl)-4,4'-bis(dimethylamino) diphenylamine sodium salt.

With regard to the concentrations not taught by Komori *et al.* the MPEP states:

"Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.")"

One of ordinary skill in the art at the time of the instant invention would have been motivated to experiment with the addition of the nitro compound and the sulfonic acid compound singly, and in conjunction, in order to test for negative results caused by an individual component before the attempting of the experiment using the two compounds simultaneously. The ordinary artisan would also have been motivated to adjust the concentrations of the compounds in order to optimize the experiment and achieve the best possible results.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one with ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence or evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Martin
Examiner
Art Unit 1655

12/2/05

PATRICIA LEITH
PRIMARY EXAMINER